

S.T.O.P. - Safe Tables Our Priority

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USDA/ FSIS Hearing Clerk
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250

Re: Docket No. 98-045N

FDA
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0074

S.T.O.P. – Safe Tables Our Priority appreciates this opportunity to comment on the federal government's strategic plan for food safety policies. S.T.O.P. is a strong supporter of the President's Food Safety Initiative. However, the organization continues to assert that the best way to ensure efficient and effective use of federal food safety resources is to create a single federal food safety agency. The development of the President's Food Safety Council contains some of the beneficial elements of a single agency. With a strategic plan and greater inter-agency cooperation, the federal food safety programs should become more efficient and effective.

S.T.O.P. is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. The organization was founded five years ago to prevent unnecessary illness and loss of life from pathogenic foodborne illness. Because S.T.O.P.'s members have been profoundly affected by the weaknesses in the existing food safety programs, the organization welcomes this opportunity to comment on the Food Safety Initiative's strategic planning process and the plan.

I. The Vision Statement

The federal food safety system has been promoted by the government as a consumer safety program. In his July 4, 1998 radio address to the public the President said "I'm doing what I can to protect our families from contaminated food." At S.T.O.P.'s January 1998 anniversary memorial service, Secretary Glickman told S.T.O.P. members "People look to their government to protect them in ways that they cannot protect themselves. That is why, as Secretary of Agriculture, there's nothing I take more seriously than the safety of America's food."

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Every American citizen is a food consumer and a tax payer, and it is the citizens' tax dollars that provide the funding for the federal food safety system. The overarching goal and top priority of the federal food safety system should be protection of public health. A food safety system which operates on consumer tax dollars and is promoted as operating for the consumer's benefit should primarily address the consumer's concerns. Since consumers pay for the system and the system has been created primarily to protect consumers, the system's agenda should be consumer driven. In section V of these comments, S.T.O.P. recommends several steps the Council can take to facilitate greater consumer participation in the food safety strategic planning process.

conflicts of interest

S.T.O.P. is deeply concerned that the nation's food safety policies are significantly weakened by food marketing and other issues that are irrelevant to food safety. The Institute of Medicine National Research Council report recognized conflicts of interests as a problem within the current food safety system, "The fact that some agencies have dual responsibilities (regulation of the quality of food products while marketing them via promotional activities) makes their actions more vulnerable to criticism regarding possible conflicts of interest **and may bias their approach to food safety.** (emphasis added)" A couple of examples to demonstrate how marketing concerns have weakened food safety policy follow:

- The government has allowed recalling entities to approve press releases informing the public about recalls.¹ During the highly publicized Hudson Foods ground beef recall, the press who knew about it took particular interest in the fact that the agency had a practice of allowing the recalling establishment to review agency press releases. An August 21, 1997 Wall Street Journal article began with this statement, "Last week, when the Agriculture Department announced what was to become the largest beef recall ever, who was it that cleared the press release? The answer: Hudson Foods Inc., the company responsible for producing the bacterial-tainted ground beef that health officials have linked to an outbreak of 16 food-poisoning cases in Colorado." Around the time that this article was published, the Secretary of Agriculture issued a memorandum to all sub cabinet officials and agency administrators informing them the industry would no longer be allowed to review agency press releases.² A year after the Secretary changed the recall notification policy, the FSIS working group on recalls recommended that USDA cede responsibility for notifying the public of recalls to the recalling entities. The working group noted in its recommendation that FDA follows a policy where the recalling company writes its own press release and is responsible for distributing it to local press. Clearly the effectiveness of recall notification has been tempered by food marketing concerns.³

¹ There is very good evidence to support the need for an unbiased party to present recall information to the public. Food industry attorney Phil Olsson noted in an April 27, 1998 Food Drug Law Institute conference on product recalls that companies have a vested interest in distributing as few press releases as possible. He also noted that establishments should regard writing a recall press release as an opportunity to put their spin on the issue. Olsson made a point of telling attendees that FSIS no longer allowed establishments to review the agency's recall press releases. Allison Beers, "Recalls Present Tough Decisions for Food Companies," *Food Chemical News*, May 4, 1998, page 19.

² Allison Beers, "Recalls Present Tough Decisions for Food Companies," *Food Chemical News*, May 4, 1998, page 19.

³ For example, a June 29, 1998 Costco press release about a recall of E. coli O157:H7 contaminated meat reads as if it were crafted to specifically contradict the agency's findings justifying the recall: "Costco has an extensive testing program to help minimize any possible risk from E. coli O157:H7 in beef sold at our

- Although the government's own consumer focus group research demonstrated that consumers are more likely to adopt good food handling practices when the risks, hazards, and prevalence of foodborne pathogens is communicated, the government has continued to promulgate consumer education messages that downplay foodborne illness risks, hazards, and prevalence.⁴

Therefore S.T.O.P. strongly urges that any reference to food marketing, promotion, hunger, nutrition, or food affordability be removed from the food safety council vision statement. The goal of the council needs to remain clear and narrow to prevent conflicts of interest that lead to weak, ineffective safety policies. The purpose of the council creation was to address foodborne illness. The Council's only goal should be preventing foodborne illness and death.

roles and responsibilities

STOP is also concerned about the last sentence in the vision statement: food is safe because everyone understands and accepts their responsibilities. The intent of this statement is unclear. Our concern is raised by the traditional efforts of the government and industry to shift responsibilities and blame for accidents on other segments of the food safety continuum.

For example, an incorrect extrapolation of CDC data has been widely cited by the industry to blame consumers for over 90% of foodborne illnesses. Although the CDC has circulated a memo explaining that this figure is incorrect, the mythological statistic is repeated to this day.⁵ Instead of using surveillance data to urge its members to be more vigilant in preventing contamination, the National Meat Association has highlighted incidents of *E. coli* O157:H7 in foods other than beef. The association recently developed statistics to downplay the well documented prevalence of the organism in ground beef.⁶ Presentations made before the Council at public meetings demonstrate this very point. Many food industry representatives invested a significant amount of time arguing about the

warehouse stores. Our internal tests and those of independent certified laboratories detected no contamination in this meat..." USDA tested Costco beef taken from the same batch eaten by an illness victim and found traces of *E. coli* O157:H7. A woman was hospitalized after consuming contaminated Costco beef. One who read the Costco press release would be unlikely to conclude that eating the product could lead to hospitalization. Under the "consumer remedy" section of the press release Costco stated, "Consumers can ensure the safety of ground beef by cooking it to an internal temperature of 160 degrees Fahrenheit." There was no mention of the fact that handling the raw product could lead to illness or death.⁴ "Most participants agreed that media messages reporting serious illness might convince them that thermometer use is necessary." (p. 18) "One theme that ran through most groups was the fear of contracting a serious disease from eating undercooked meat or poultry. Informing the public through public awareness campaigns that describe and explain outbreaks of foodborne illness was thought to be a powerful motivator for behavior change." Patrick Koepl, "Final Report: Focus Groups on Barriers that Limit Consumers' Use of Thermometers when Cooking Meat and Poultry Products," January 1998, pages 4, 23, 18, 42, and 44.

⁵ "Recently, a statement was made, purportedly quoting CDC data, that 'the food processing industry is involved in less than 10% of reported foodborne disease outbreaks of known origin...' The statement is a gross misinterpretation of data in a paper by Bean and Griffin in the *Journal of Food Protection* in 1990." Memorandum to the record from the Acting Chief, Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, NICD, July 21, 1995.

⁶ National Meat Association "USDA Reports on Foodborne Illness," *Lean Trimmings*, March 17, 1997. National Meat Association, "Assessing *e. coli* O157:H7 in Ground Beef," *Herd on the Hill*, November 2, 1998. National Meat Association "E. coli O157:H7 -- the Odds," *Lean Trimmings*, November 30, 1998.

validity of the surveillance numbers instead of describing the actions they will take to reduce food contamination.

In an ideal world everyone would know what their responsibilities are and assume them. But as policy makers should know all too well, we do not live in an ideal world. Food safety laws were created to address practices in food plants that compromised public health. The meat inspection laws were created in response to publication of *The Jungle*, an expose about the filthy Chicago meat packing industry. Revision of antiquated meat and poultry regulations didn't occur until a major outbreak of *E. coli* O157:H7 significantly raised awareness about food safety.

The role of the government is ensuring that responsibilities for public health and safety are assumed and carried out by the food industry. Promotion of voluntary public health and safety measures should not reduce or replace vigorous enforcement of food safety laws and regulations. Consumers have little access to food growing and processing areas. Taxpayers expect the government to monitor on their behalf these often inaccessible steps of the food chain. Secretary Glickman recognized this in his remarks at the S.T.O.P. memorial service, "People look to their government to protect them in ways that they cannot protect themselves."

As stated earlier, conflicts of interest mitigate food safety policies. The public doesn't trust the industry to regulate itself. The government has historically recognized that those with an interest that may conflict with the laws adopted for the public's good should be regulated to ensure that the public is served and that commercial practices are conducted legally. Consumers expect to have food safety laws enforced and they expect a neutral, third party to be responsible for enforcing these laws. Participants in a 1998 USDA sponsored focus group said they trust government inspection to prevent contamination of products before they reach the marketplace.⁷

Consumers also expect to have a minimum standard of food safety enforced consistently across the United States. Consumer attitudes research conducted by Celinda Lake for Citizens for Sensible Safeguards revealed that consumers expect to have the same level of food safety wherever they are within the U.S. They expect a cheeseburger purchased in Texas to be as safe as one purchased in Maine.

Unfortunately, there isn't a single food safety law enforced consistently across the country. And state meat inspection programs have demonstrated how local concerns can mitigate enforcement of national food safety laws and place consumers at risk. In an October 1998 Topeka Capital-Journal article, the Kansas Secretary of Agriculture noted that the state inspectors had difficulty enforcing federal laws in local plants "In many situations, the inspectors live in the same community as the people they regulated. They inspect people. They inspect people's livelihood. These are tough decisions."⁸ The chair woman of the Kansas House Agriculture Committee explained to the Topeka Capital-Journal that the state should retain the costly state inspection program because it gives Kansas the "home team" advantage.⁹ The head of the Florida state meat inspection program had a

⁷ Patrick Koeppl, "Final Report: Focus Groups on Barriers that Limit Consumers' Use of Thermometers when Cooking Meat and Poultry Products," January 1998, pages 14, 26, and 42.

⁸ Christie Applehantz, "Ag Boss Trying to Rescue State's Meat Program," *Topeka Capital-Journal*, September 20, 1998

⁹ Christie Applehantz, "State Hopes Meat Program Gets a 'Well Done,'" *Topeka Capital-Journal*, October 4, 1998.

similar attitude, "We're patient with small businesses...I would venture to say that 50% to 60% of these [processors] would go out of business under federal inspection."¹⁰

The Government should honestly convey to the public what it does and does not do with regard to food safety. For instance, if risk assessments and cost benefit analysis are going to be used to determine the level of government oversight and enforcement of food safety laws, the public should be told what conditions are triggering oversight and enforcement. In addition, the public should know what level of foodborne illness and death the government is willing to ignore before addressing weaknesses in the food safety laws and regulations.

accountability

Consumers expect the government to provide a prevention based food safety system that is verified to be effective. Just as publicly traded companies must be held accountable to their stockholders, the government should be held accountable to the public that funds its activities. S.T.O.P. encourages the President's Food Safety Council to facilitate the creation of regular evaluation reports that document food safety enforcement actions and policy changes. These reports should be issued in conjunction with national foodborne illness epidemiological data and assessments of emerging foodborne pathogens. The USDA's Food Safety and Inspection Service Quarterly Regulatory and Enforcement Reports provide a good example of the type of evaluation document that should be issued.

II. Barriers and Gaps Impeding Food Safety Policies

S.T.O.P. recognizes many of the food safety gaps the NAS committee highlighted in its report. We agree that food safety efforts are not adequately funded, that food safety laws should be harmonized so that similar risks are addressed consistently and effectively, that current surveillance efforts are not sufficient, that additional food safety research is needed, and that current consumer education efforts fail to change behavior.

conflicts of interest

As previously noted, the vision statement itself includes a barrier to improved execution and coordination of food safety policies: marketing and promotion concerns verses public health concerns. The NAS report also recognized the conflict of interest barrier to more effective food safety policy.¹¹ The vision must be confined to food safety issues in order to be effective.

If agricultural marketing and promotion issues remain as components of the Council's purview, they will dilute the Council's food safety work. To illustrate how food marketing concerns led to reduced public health protection and to loss of consumer confidence one can review the British BSE crisis. The United Kingdom's Chief Medical Officer recently testified that his statement regarding the safety of eating beef was altered by the Ministry of Agriculture to downplay legitimate concerns about product safety. Marketing concerns over-ruled public health concerns.¹² When consumption of beef was

¹⁰ Pat Beall, "Consumer Groups Decry State Meat Inspection," *Wall Street Journal (Florida Journal)*, July 17, 1996.

¹¹ Committee to Ensure Safe Food from Production to Consumption, "Ensuring Safe Food: From Production to Consumption," Institute of Medicine National Research Council, National Academy Press, Washington, DC 1998, page 8.

¹² "Former CMO 'Did Not Approve Safe Beef Message,'" *PA News*, October 30, 1998.

linked to CJDnv in the UK, public confidence in the government and the industry plummeted. Demand for British beef diminished by 36%.¹³

fragmented federal food safety program

The current food safety system is fragmented across USDA, HHS, EPA and DOC. At least six federal agencies have responsibility for food safety: FDA, CDC, FSIS, ARS, CSREES, and EPA. In addition, there are over 50 state and local public health departments that monitor foodborne illnesses under diverse regulations and laws. State and local public health departments are also enforcing retail food safety under various statutes and regulation. S.T.O.P. agrees with the NAS committee assessment that "inconsistent, uneven and at times archaic food statutes that inhibit use of science-based decision making in activities related to food safety..." and that lack of integration among federal agencies and among the federal and state agencies is inhibiting the implementation and enforcement of good food safety policies.¹⁴

There are certain segments of the food safety chain that have been virtually ignored, particularly the farm, the ranch, and product in transit. Produce growing and processing, which is under the jurisdiction of FDA, has not received adequate government oversight. FDA conducts no inspections on farms except in response to a foodborne illness. FDA and FSIS are still trying to determine which agency is responsible for inspecting food in transit. And although treatment and disposal of human sludge is closely monitored by EPA and animal manure is frequently a vehicle for pathogen contamination of produce, there are no federal rules or regulations preventing the direct application of pathogen harboring manure on human food crops. The present food safety system does not extend from farm to table, it ignores some of the most obvious contamination entry points of the food chain.

inconsistent enforcement and varying enforcement philosophies

Current federal agency food statutes do not allow the consistent enforcement of food safety policies. Different policies are applied by varying agencies to foods posing similar risks. For example, FSIS has a proactive inspection program to address meat and poultry adulteration. All meat and poultry carcasses must be inspected and approved by a federal inspector before entering the market place. FDA has a passive inspection program. Seafood establishments, which handle food with risks similar to those of meat and poultry, are subject to approximately one inspection per year. FSIS inspectors are in every meat and poultry plant in the U.S. every day. FDA made a goal of inspecting all seafood establishments in one year.¹⁵

Similar food safety regulations for products that pose similar risks are enforced in an inconsistent manner. For example, FDA and FSIS have developed HACCP-based inspection for meat, poultry and seafood. The FSIS HACCP regulation includes pathogen performance standards, but the FDA HACCP regulation does not. FDA's regulatory philosophy is dramatically different from that of FSIS. FDA officials told the industry that the first seafood HACCP inspection is conducted with the purpose of educating the industry while FSIS's first year of large meat and poultry plant HACCP inspections were conducted with the purpose of enforcing the law.

¹³ Peter Cunliffe, "BSE Crisis 'Cost Nearly \$1B in First Year,'" *PA News*, March 13, 1998.

¹⁴ Committee to Ensure Safe Food from Production to Consumption, "Ensuring Safe Food: From Production to Consumption," Institute of Medicine National Research Council, National Academy Press, Washington, DC 1998, page 9.

¹⁵ Adrienne Dern, "Food Safety Initiative Programs Targeted for Launching in 1999," *Food Chemical News*, June 15, 1998, page 7.

The effectiveness of these enforcement philosophies is obvious. FDA's goal was a 50% failure rate, but by mid-May 1998 the failure rate was 70%.¹⁶ USDA, on the other hand, took a firm stance on HACCP compliance. Secretary Glickman made it clear that the new inspection program at USDA would be fully enforced from day one "Our new meat and poultry inspection system will begin to take effect next week....And I want to make one thing perfectly clear -- we will be watching. If you're out there producing dirty product -- what we would call a repeat violator, from now on -- don't expect a thousand chances to get it right."¹⁷ USDA's strong stance was evident in compliance results. In the first three quarters of USDA HACCP implementation in large plants, the compliance rate was 92%.¹⁸

inconsistent state and local laws, regulations, and enforcement

Inconsistent state food safety programs also impede the formation of a seamless, national food safety program. Some states have adopted laws or maintained policies that counter food safety efforts. For example, agricultural disparagement laws are cited by some public health department officials as a barrier to releasing foodborne illness or outbreak information. The FSIS working group on recall report reveals that in three out of five E. coli O157:H7 retail contamination and recall incidents, state agencies chose not to notify the public of the contamination or recall.¹⁹

Another state food law that counters food safety is the permissive sale of dangerous food products. Most states have banned the sale of raw milk, which has been repeatedly linked to E. coli O157:H7 illnesses; but a few continue to allow the sale of this very risky and hazardous product.

Retail food safety is a very important link in the food chain -- often the last link before food is consumed.²⁰ Yet retail food inspection is governed by state and local entities that enforce a patchwork of different food safety statutes and regulations. FDA's model inspection Food Code has been cherry picked to reflect the agribusiness biases within each state or locality. S.T.O.P. doubts it will ever be universally and wholly adopted and enforced without stronger federal incentives for states and localities to do so.

State meat and poultry inspection enforcement demonstrates the very regulatory attitudes which cause consumer concern about local enforcement. Although state regulators are supposed to enforce federal standards, this is often not the case. There is a bias at the state and local level to not impede local businesses. This attitude leads to lenient inspection and enforcement of regulations. A quote from the executive director of the Kansas Meat Processors Association regarding Kansas state inspection demonstrates this point: "Things the state has not checked us on in 30 years, the federal does. ...It's like living in two

¹⁶ Natalie Pargas, "FDA's Kraemer Identifies Four Major Research Areas for Seafood HACCP Implementation," *Food Chemical News*, July 13, 1998, page 8.

¹⁷ Secretary Dan Glickman, remarks at the 5th Anniversary of the Pacific Northwest Outbreak, Chicago, IL, Release No. 0022.98, January 18, 1998.

¹⁸ USDA, "Food Safety and Inspection Service Quarterly Regulatory and Enforcement Report," July 1, 1998 to September 30, 1998, page 1.

¹⁹ USDA, FSIS, "Improving Recalls at the Food Safety and Inspection Service: Report of the Recall Policy Working Group," 1998, page 40.

²⁰ According to the ERS, 56% of Americans eat away from home each day. L. Borrud, C. Wilkinson Enns, and S. Mickle, "What we Eat in America: USDA Surveys Food Consumption Changes," *Food Review*, September-December 1996, page 18

different worlds.”²¹ The Wall Street Journal documented this disparity in a story about Florida’s meat inspection program.²² Even some in the food industry have recognized the difference. During a discussion of USDA’s National Advisory Committee for Meat and Poultry Inspection, David Theno of Foodmaker remarked, “My experience in reviewing some of these state facilities, and I’ve looked at them before in terms of local supply and things, is that there is some disparity...I’ve seen disparity in what I would call a federal plan and a state plan.”²³

inconsistent foodborne illness surveillance and response

Surveillance of foodborne illnesses is uneven. FoodNet cites make a horse shoe around the upper rim of the nation: California (part of state), Oregon, Minnesota, New York (part of state), Connecticut, Maryland (part of state), and Georgia (part of state). FoodNet has no to very little data on illnesses in the Southwest and Midwest sections of the U.S.

Surveillance of foodborne illness is mostly dependent upon a passive, inconsistent volunteer reporting system. The patchwork of state foodborne illness reporting policies degrade the quality of national statistical data. All states are not reporting the same diseases to CDC. While some states monitor E. coli O157:H7 illness, some do not. At this time, Pennsylvania, Wisconsin, Virginia and Hawaii are not E. coli O157:H7 reporting states.²⁴

The statistics gathered are based on voluntary compliance to reporting laws. Although it is frequently acknowledged that physicians often do not report illnesses to public health agencies, we are unaware of any adoption of incentive or disincentive programs to facilitate reporting. S.T.O.P. is concerned that the government is fostering more dependence on risk assessment while continuing to ignore the barriers to collecting more reliable data.

Public health department policies and capacities vary state by state. Some states count individual illness cases while others only count illnesses associated with outbreaks. Some states have the capacity to conduct PFGE or DNA finger printing of foodborne pathogens while others do not. At this time only 14 states and New York City are participating in PulseNet. Some states reserve PFGE testing for cases arising from particular circumstances. Many S.T.O.P. victim members expressed anger when they learned that their state was part of PulseNet, but the public health department did not employ this technology during the investigation of their illness.

Responses to foodborne illnesses vary in accordance with local and state laws. S.T.O.P. frequently hears victim complaints about local public health department handling of illness cases. Most often, victims complain that state health departments did not aggressively pursue the source of contamination. Frequently, state health departments do not investigate individual cases of illness. They reserve their resources for outbreaks. Even in cases where the source was investigated and the food vehicle identified, victims were shocked to learn that no measures were taken to alert the public to the problem so that

²¹ Christie Applehantz, “State Hopes Meat Program Gets a ‘Well Done,’” *Topeka Capital-Journal*, October 4, 1998.

²² Pat Beall, “Consumer Groups Decry State Meat Inspection,” *Wall Street Journal (Florida Journal)*, July 17, 1996.

²³ USDA transcript of the National Advisory Committee for Meat and Poultry Inspection, Docket No. 97-044N, Washington, DC, September 10, 1997, page 196.

²⁴ Table II Provisional cases of selected notifiable diseases, United States weeks ending November 7, 1998, and November 1, 1997 (44th Week),” *MMWR*, November 13, 1998.

others would be informed of the risk and seek necessary medical attention. In many cases the responsible party was not penalized in any way for causing harm to the public.

Those who have suffered from contamination often are not treated like customers by state and local public health departments. Frequently, they are told very little about the foodborne illness investigation, if there even is an investigation. Sometimes the cause of illness or death is not disclosed to the victim or the victim's family. S.T.O.P. has at least two members from unrelated illness incidents who learned the cause of their children's deaths by listening to news broadcasts on the radio.

Victims have little recourse when health departments do not respond appropriately to their cases. There is no higher body to which they may appeal that will re-evaluate the situation in time to conduct a meaningful investigation. It is a widely held belief that the CDC is the nation's public health department and that they have jurisdiction over state health departments. Most S.T.O.P. victims learned the hard way that CDC may only investigate illness incidents when state agencies invite their participation.

Some states alert the public of food recalls by issuing press releases that include the brand name of the contaminated food and its source. As mentioned in the preceding section, other states choose not to release retail recall information to the public. The first child to die in the 1993 Jack in the Box outbreak resided in the same county as the restaurant chain's parent company. The family was not informed of the actual cause of death, no effort was made to alert the public to potential additional cases, and no effort was made to investigate whether the contaminated product was distributed to other retailers. Several weeks later, at least three more children died, at least 195 people (mostly children) were hospitalized with HUS, and over 700 people suffered illness from tainted Jack in the Box burgers sold in four states.²⁵

inconsistent and inaccurate consumer education information

The NAS report noted that consumer education "often fails to influence behavior."²⁶ S.T.O.P. asserts that most industry and government consumer food safety education has been conducted in an ineffective manner. Although the government's own consumer research has indicated that consumers will adopt food safety precautions in response to illness reports, the government and industry have repeatedly disseminated messages that downplay food risks, food hazards and pathogen prevalence. S.T.O.P. suspects the reluctance to include honest communication of foodborne illness risks, hazards and prevalence stems from the conflict of food marketing and food safety roles within the federal government.

The government's own pathogen baseline tests indicate that Salmonella and Campylobacter are rampant in the food supply. USDA's ground chicken survey detected Salmonella in 44.6% and Campylobacter in 59.8% of the samples taken.²⁷ USDA's ground turkey survey found Salmonella in 49.9% and Campylobacter in 25.4% of the samples taken.²⁸ This information was gleaned through research funded by taxpayer dollars to further their interest. At the very least, this information should be used in

²⁵Jean Buzby et. al, "Bacterial Foodborne Disease: Medical Costs & Productivity Losses," ERS, Report No. 741, August 1996, page 29.

²⁶ Committee to Ensure Safe Food from Production to Consumption, "Ensuring Safe Food: From Production to Consumption," Institute of Medicine National Research Council, National Academy Press, Washington, DC 1998, page 9.

²⁷ USDA, FSIS, "Nationwide Raw Ground Chicken Microbiological Survey," May 1996.

²⁸ USDA, FSIS, "Nationwide Raw Ground Turkey Microbiological Survey," May 1996.

consumer education campaigns to convince consumers that they should handle food properly every time they cook or eat. It is in the public's best interest to know the prevalence of pathogens in the food supply. S.T.O.P. believes consumers would be more likely to use good handling practices if they understood that approximately half of the ground poultry products they purchase are contaminated with organisms that cause foodborne illness.

At this time, FSIS presents information about E. coli O157:H7 by stating: "E. coli O157:H7 is a potentially deadly pathogen that can cause bloody diarrhea and dehydration. The very young, the elderly, and persons with compromised immune systems are the most susceptible to foodborne illness. E. coli O157:H7 bacteria have been implicated in several recent outbreaks of foodborne illness across the United States." S.T.O.P. E. coli O157:H7 victims have experienced liver failure, heart attacks, seizures, blindness, paralysis, brain damage, kidney failure, and death. Approximately one out of five E. coli O157:H7 victims requires hospitalization. The government's information downplays the negative outcome of E. coli O157:H7 by emphasizing bloody diarrhea and dehydration and noting that E. coli O157:H7 is "potentially deadly." The serious ramifications of E. coli O157:H7 are limited to a couple of adverbs in this statement. More Americans would be motivated to implement recommended food safety precautions if they understood that one out of five E. coli O157:H7 victims require hospitalization and that some victims suffer severe and permanent health consequences.

The government's message doesn't explain to the public that individuals susceptible to illness include pregnant women, people using antibiotics, alcoholics, and people using antacids. In emphasizing susceptible populations, however, the government shouldn't imply that healthy adults can't contract severe cases of E. coli O157:H7 illness and die. Although E. coli O157:H7 and other foodborne illnesses most often strike children, S.T.O.P. is composed of numerous adult E. coli O157:H7, Listeria, Campylobacter, and Salmonella victims.

At the very least, education messages conveyed to consumers should be accurate. We are disappointed that advice to cook hamburgers until "no longer pink" (i.e. brown) is still distributed to consumers. The government's own studies have proven that a significant portion of ground beef prematurely browns when cooked at low temperatures.²⁹ Approximately one out of every ten hamburgers cooked in the U.S. will turn brown before reaching 160 degrees F. The only advice consumers should receive regarding cooking ground beef is: cook it until it reaches 160 degrees F.

focus efforts on the pathogens

In order for the government to address food safety, it must shift its focus to microorganisms that cause human illness and it must have a means of comparing the effectiveness of one pathogen control system to another. The government should be doing more to detect pathogens in food. FSIS meat and poultry HACCP should incorporate Campylobacter performance standards as soon as possible. FDA Seafood HACCP should incorporate pathogen testing. FDA's juice program should include a random sampling program for E. coli O157:H7 similar to the FSIS E. coli O157:H7 random sampling plan for ground beef. Pathogen testing verifies that food safety systems are working and facilitates voluntary industry testing. The FSIS random sampling program for beef significantly increased E. coli O157:H7 positives from a high of four positives in one year

²⁹ D. Soderberg and M. Hoffman, "An FSIS/ARS Study: Premature Browning of Cooked Ground Beef," August 10, 1998.

to 14 positives in FY98 when it shifted its focus to plants that are not actively testing for this pathogen.

More reliable and rapid pathogen tests need to be developed. Quantitative tests for food pathogens need to be developed to move towards an infectious dose based performance standard. Rapid tests are needed to achieve results before product is released into the market place.

Good decisions are made upon good information. Speed and accuracy are key to epidemiological investigations and recalls. The improvement of test accuracy and sensitivity will lead to quicker and more confident decision making in cases that indicate a potential public health threat.

Microbial baselines should be established for risky foods. Baselines provide objective and meaningful information with which food safety systems can be evaluated. Each segment of the food safety chain and each oversight area needs baselines. For example, state inspection programs should have baselines for each state inspected product. Baselines of a particular food should reflect pathogen loads at the producer, processing, distribution, retail, and consumer levels. Without baselines, it will be difficult to gauge which programs are effective and what segments of the food safety chain require greater attention. As baselines and quantitative tests are developed, more pathogen performance standards should be adopted. Pathogen standards should be set slightly below the infectious dose for the most vulnerable population.

industry accountability and anonymous food

No unlabeled food should be sold within the United States. Anonymous food interferes with effective trace back in cases of foodborne illness and effective recall of contaminated product. Allowing un-branded food in the market place does nothing to instill one important government food safety objective: getting the industry to take responsibility for food safety.

It is widely acknowledged that foodborne illnesses are rarely traced to their source. The sources of even the most wide spread and publicized illnesses (Jack in the Box and Hudson Foods) were never definitively determined. Between 1982 and 1996, 139 outbreaks linked to ground beef were reported to CDC. For fourteen years, there were an average of approximately 10 ground beef outbreaks per year. Only one outbreak has ever been linked to the farm or ranch.³⁰ Without accountability, the food industry can easily evade responsibility for food products served to millions of Americans.

All food products should be labeled with a brand name, farm of origin, and subsequent processing information. The UK has recently adopted a nation-wide bovine tracking system, one Colorado meat company has a bar code system that tracks food products from the individual animal to the final product, and FDA requires origin labels on molluscan shellfish to identify the harvester, date of harvest, and location of harvest.³¹

Recalls of un-branded foods are less effective. The lack of food labeling prevents consumers and retailers from identifying recalled food. Recalled un-branded foods are

³⁰ Gregory L. Armstrong, Jill Hollingsworth, and J. Glenn Morris, "Emerging Foodborne Pathogens: *Escherichia coli* O157:H7 as a Model of Entry of a New Pathogen into the Food Supply of the Developed World," *Epidemiologic Reviews*, Vol. 18, No. 1, 1996, page 37.

³¹ FDA, "1997 Food Code," sections 3-202.17, 3-202.18, and 3-602.11.

more likely to remain on grocery store shelves and consumer pantries, and therefore are more likely to lead to increased injuries and fatalities.

biased food advisory committees

Currently, the federal government relies upon advisory committees to elicit comments on various food safety proposals, but frequently the committee composition is unbalanced. Although the consumer community has nominated candidates, the influential National Advisory Committee for Microbial Criteria for Foods has no consumer representation. The National Advisory Committee on Meat and Poultry Inspection has three consumer and seven industry representatives. To obtain well rounded counsel that reflects the input of all constituencies, membership on federal advisory committees should be balanced.

Further, there are no requirements for advisory committee participants to disclose information that would demonstrate a potential conflict of interest, such as receipt of food industry research funding, investment holdings in agribusinesses, or receipt of food industry consulting fees. The FDA requires researchers who test drugs and medical devices to disclose financial ties to the manufacturers. Major medical journals such as the New England Journal of Medicine and schools such as the Johns Hopkins School of Medicine have adopted conflict of interest policies. Members of government advisory committees significantly influence federal food safety policy. The public and the government should know whether those officially influencing national food safety policy are doing so with any temptation to recommend what is in the best interest of themselves or their employer.

lack of accountability to the public

Currently there isn't an adequate feedback mechanism for the food safety agencies' customers to assess the government's performance. While companies, trade associations and unions often utilize formal opportunities to evaluate agency performance, average citizens rarely read the Federal Register. S.T.O.P. urges the federal government to re-examine its processes for soliciting comments on food safety policies from the public.

S.T.O.P. suggests that President Food Safety Council public meetings regarding food safety priorities be held after business hours or on weekends. If the public meetings must be held on a weekday, it should be a Friday. Members of the public taking time from work to participate would be more likely to fly to a meeting on a Friday to get a cheaper Saturday stay-over ticket. The meetings should be set well in advance, perhaps with an identified day and month each year, such as the first Friday in March.

As mentioned in a preceding section of this document, S.T.O.P. recommends that the government issue at least an annual report presenting information about federal enforcement and regulatory actions pertaining to food safety. This report should be released in conjunction with latest epidemiological information on foodborne illnesses and pathogen emergence.

government commitment

Every federal employee at each food safety agency must understand and support the nation's food safety mission. The messages and policies developed at the top need to be delivered and enacted throughout the agencies' ranks. S.T.O.P. was very concerned to learn that a year after the Hudson Foods outbreak and recall, a year after the Wall Street Journal publicized USDA's policy of allowing recalling industries the opportunity to

review press releases regarding their own recalls, and a year after the Secretary of Agriculture sent a memo to agency staff informing them that no industry review of further recall press releases would take place, the FSIS' own working group on recalls formally recommended that the recalling entities be solely responsible for issuing press releases about the recall. Clearly the Administration's food safety philosophy has not been grasped deeper within the agency. S.T.O.P. suspects, again, that the duel and opposing marketing and inspecting responsibilities of the departments are the root of the problem.

Information must flow down from the administration and up from the field. Those enforcing the laws and regulations should have the opportunity to provide feedback to the agencies. S.T.O.P. recommends that food safety agencies, as a part of their suggested yearly evaluation, hold a focus group with a randomly selected portion of the field work force to discuss ways in which the agency can improve regulations and their implementation.

lack of food safety administrators

There are few people who possess both public health and food science credentials. Government research and scholarship programs should encourage the development of experts with both of these credentials. The lack of overlap between these two disciplines is evident in the hamburger cooking consumer education campaign. Public health experts have collected data correlating consumption of hamburger based on the assumption that pink hamburgers are uncooked and brown hamburgers are cooked. Food scientists have demonstrated that pink hamburgers are frequently cooked thoroughly and brown hamburgers frequently are not thoroughly cooked. If the two disciplines were more intermingled, both disciplines could work more effectively and efficiently.

III. Changes Needed to Meet Vision Statement Goals

A. Government Agencies

1. Federal

- There needs to be an independent, single food safety agency.
- Federal food safety agencies should not only require conflict of interest disclosure for advisory committee members, but also require that the research on which government policies are based be limited to articles published in scientific journals with financial disclosure or conflict of interest policies. To develop sound food safety policies, the government should rely upon unbiased data. In order to determine whether study results may be biased, one should rely on information published in journals with disclosure requirements.
- A single agency, preferably the CDC, should compile foodborne illness and outbreak information on an ongoing basis. This information should be shared with food safety agencies and the public in a timely manner. Outbreak and illness information should be broken down by pathogen and food type. This information should be available on agency web sites and it should be distributed to interested constituents through a "Constituent Update" type publication. The agencies should distribute the food type organized information to industries and industry trade associations that produce food linked to particular pathogens. This list should also be distributed to agency employees.
- Consumers expect to have consistent food safety laws and regulations across the nation. The federal government should encourage that state and local agencies adopt minimum, consistent food safety requirements (such as the Food Code), remove

obstructive state and local food safety laws and regulations (such as agricultural disparagement laws), and provide a minimum standard of public health protection (such as PFGE testing capacity in each state) by providing positive and negative incentives to meet these minimum standards. For example, the federal funds for state agriculture inspection programs should only be granted in states that adopt the Food Code, remove agricultural disparagement laws, require reporting of all foodborne illnesses tracked by the CDC, outlaw the sale of raw milk, and meet or demonstrate the will to meet the minimum standards within the CDC public health department core capacity document (this document outlines the minimum standards state and local public health departments should adopt). State agencies seeking federal dollars should provide four items to the federal government: an annual report on food safety enforcement (similar to the quarterly inspection enforcement reports prepared at USDA), copies of all consumer generated agency evaluations, the state's microbial baseline studies for state inspected products (should cover the same microorganisms tracked by the federal government under their inspection of these products), and annual foodborne illness surveillance information for the state.

- Federal agencies need to harmonize their work. All of the food safety programs should address similar food risks in a consistent manner. For example, an adulterant recognized by FDA should be recognized as an adulterant at FSIS. FDA should have a proactive seafood HACCP inspection program similar to FSIS' meat and poultry HACCP inspection program. The FDA HACCP program should include microbial testing and pathogen performance standards as the FSIS HACCP program does.
- The federal agencies should have jurisdiction at the farm and distribution levels. An agency should take responsibility for manure control and develop regulations to ensure that only pathogen free manure is applied to food crops.
- If the government is striving to improve its performance, it needs to ask those it serves to evaluate their work. To facilitate meaningful public comment, the government should follow up with a random sample of individuals that it has served (such as consumer hot line callers or illness victims) and ask these consumers to evaluate the government's handling of their cases.
- The federal food safety agencies should require brand and origin labeling for all consumer food products.
- FDA food establishments should be required to register with the government. The agency currently doesn't have a list of all of the entities that it is responsible for inspecting.
- Federal agencies should incorporate more microbial testing and performance standards into their inspection programs. Microbial baseline studies should be ongoing. Once quantitative pathogen tests are developed, pathogen standards should be set slightly below the infectious dose for the most vulnerable populations.
- The federal government should ensure that its food safety education messages are consistent and accurate. Risks, hazards and pathogen prevalence should be presented in a forthright manner to facilitate more widespread adoption of good handling practices.
- The federal government should conduct an assessment of industry compliance with food safety laws and regulations. This assessment should determine the average deviation from food safety laws and regulations. The information gathered would be useful in determining performance standards and developing regulations.

2. State and Local

- State food safety enforcers should be under the jurisdiction of public health departments rather than state departments of agriculture. This would limit the influence of food marketing concerns on food safety policy decisions.
- To increase the probability that local agencies are addressing consumer issues, state and local agencies should institute food safety advisory committees that include balanced representation from the industry, public health professionals, and consumers.
- States should also require conflict of interest and financial disclosure for food safety advisory committee members. States should recognize research that is conducted by researchers in institutions that have conflict of interest policies or is published in scientific journals with conflict of interest and financial disclosure policies.
- State rules and regulations should be consistent with federal food safety rules and regulations. For example, all state meat and poultry inspectors should be enforcing FSIS HACCP regulations in large state inspected plants. All states should adopt the Food Code in its entirety.
- States conducting parallel inspection programs should have food by food baseline studies for all microorganisms monitored by the federal government. For example, state meat and poultry inspection agencies should collect *Campylobacter* baseline information in the same manner and at the same time of year that FSIS collects this data for meat and poultry. This would make the state and federal data comparable and allow for the evaluation of the performance of each system in contrast to the other.
- State agencies should have consumer comment feed-back loops incorporated into their food safety work. The agencies should have regular consumer evaluations.
- The state and local governments should ensure that their food safety education messages are consistent and accurate. Food risks and hazards and pathogen prevalence should be presented in a forthright manner.
- The state food safety agencies should conduct a risk assessment study on industry compliance with state food safety laws and regulations. The study should control factors that may affect performance, such as number of employees or seasonal work. This assessment should determine the average deviation from food safety laws and regulations for the business types studied. The information gathered would be useful in developing state based performance standards and regulations.
- The CDC should have the authority to be involved in every illness and outbreak investigation in which the illness victim requests their assistance.

B. Industry

- The industry should share microbial and consumer complaint data with regulating agencies.
- Industry trade associations should share illness and outbreak data with their members. Data should be used to educate members about the risks in products they produce or process.
- Food industries should be marketing food safety. Competition based on safety will increase safety overall. In order for market forces to work, all products should bear brand name and origin information.
- The industry should focus its attention on its own food safety problems. Instead of shifting blame for foodborne illnesses on other segments of the food safety continuum, the industry should address the weaknesses within its own area of responsibility. For

instance, instead of arguing that consumers are responsible for foodborne illness and embarking on consumer food safety education efforts that downplay risks, hazards, and pathogen prevalence, the industry should work to effectively educate and train its own personnel and to ensure that food handling practices are employed every time food is handled under their care. It is not enough to educate employees about safe handling practices, businesses must ensure that management requires the application of safe handling practices. Trade associations should be teaching their members HACCP, informing members of risks associated with their food products, and sharing the latest relevant scientific advances for pathogen detection and control.

C. Public Health Professionals

- Public health officials should agree on minimum standards that state and local public health agencies should meet to run effective programs. This is underway through the CDC's core capacity effort. Once core capacity standards are achieved, public health officials should encourage their adoption in each state.
- Public health departments need to incorporate consumer evaluation into their programs.
- Public health officials need to provide the public with food safety information that will prevent illnesses and deaths. For example, agencies should issue press releases regarding outbreaks and recalls likely to affect state residents. Consumer messages should be unbiased and accurate.
- State public health officials should provide foodborne illness victims with all relevant information regarding their illnesses and the investigation of their illnesses.
- State public health agencies should quickly and aggressively pursue the cause of every foodborne illness brought to their attention.

D. Consumers

- Consumers should read warning labels on foods and take necessary precautions.
- Consumers should read and follow safe handling instructions on foods.
- Consumer organizations should inform consumers about foodborne hazards, risks and pathogen prevalence.
- Consumer organizations should educate the public about steps they may take to reduce the likelihood of contracting illness.

E. Congress

- Congress should grant USDA and FDA mandatory recall authority.
- Congress should grant USDA and FDA the authority to assess civil fines and penalties on violators of food safety laws.
- Congress should give FDA the authority to inspect imported food in a manner similar to USDA import inspection.
- Congress should grant USDA and FDA the authority to regulate farming and animal husbandry practices that are demonstrated to influence food safety.
- Congress should give food workers whistle blower protection.
- Congress should provide food safety agencies with adequate funding to meet consumer expectations of the food safety agencies.

- Congress should prevent members with financial interests in agribusiness from serving on agriculture-related committees.

IV. Short-term and Long-term Goals

A. Short-term

- Require brand and origin labeling on all consumer food packages.
- Develop and implement manure control regulations.
- Require FDA regulated establishments to register with FDA. Registration should also include a small processing fee towards maintenance of the FDA registration database and document management.
- Federal and state governments should embark on baseline studies for foodborne pathogens in risky foods, such as *Campylobacter* in meat and poultry.
- The federal government should begin implementing a state food safety funding incentive program. The obstacles to effective food safety systems and the core elements of state food safety programs should be determined.
- The federal and state agencies should incorporate feed back mechanisms in their food safety programs to elicit consumer evaluations, particularly from foodborne illness victims.
- Federal and state agencies should revise consumer education messages to incorporate accurate information that facilitates adoption of good handling practices. These messages should inform the consumer of illness ramifications and provide information that allows the consumer to determine the level of risk products poses to him or her.
- Federal and state agencies should adopt conflict of interest and financial disclosure policies for research and advisory committee participation.
- FoodNet sites should be expanded to cover the Southwest and Midwest.
- Federal and state agencies should provide foodborne illness statistics and pathogen emergence information to industry and trade association representatives.
- A federal agency, preferably the CDC, should develop a foodborne illness outbreak and illness cases list that is continually compiled and regularly disseminated. This list should incorporate information gathered on foodborne illnesses in each state.
- Research rapid and quantitative pathogen tests.
- Establish criteria for evaluating and approving consumer pathogen interventions such as produce washes.
- Conduct assessments of industry compliance with food safety laws and regulations.

B. Long-term

- Establish a single food safety agency.
- Harmonize food safety laws and regulations.
- Conduct research needed to detect pathogens such as Hepatitis A and *Cyclospora* in foods.
- Acquire mandatory recall authority, farm and ranch regulatory jurisdiction and the authority to assess civil fines and penalties.
- Develop performance standards for additional pathogens.
- Provide whistleblower protection for plant employees.

Facilitate the development of public health/food science experts.

V. Improving Public Involvement in Development of Government Food Safety Policy Making

There should be more outreach to consumers in order to elicit their participation in rule making and public meetings. S.T.O.P. recommends that public meeting and proposed rules be distributed to interested parties in a weekly "Constituent Update," such as the one prepared and distributed via fax by FSIS. This update is more user friendly because it is short and written in plain language. It could also be distributed to a greater number of consumers through email. It would be best if *all* food safety related government announcements were combined in a single, weekly "Constituent Update" type document.

To increase public participation in meetings, they should be held when average consumers can attend. So far President Food Safety Council public meetings have been scheduled during business hours, which are most convenient for full time lobbyists and trade association representatives. We recommend that the Council hold public meetings on weekends or after business working hours.

Government food safety agencies should follow up with consumers who have filed complaints with the agencies or with illness victims to get their feedback on the agency's handling of their concerns. Constituent feedback is often gathered for other government programs. For example, many state WIC departments regularly poll their constituency to assess whether WIC benefit recipients have suggestions for improving the system.

Public meetings should be announced at least two months in advance to give consumer constituents enough time to plan participation. It would be best if meetings were held regularly and scheduled on a fixed date. For example, the Food Safety Council could establish a yearly public meeting for consumer input during the first Friday of a specified month.

The federal government could create a consumer advisory panel to provide the consumer's perspective on issues raised by the committee. Participation in the panel should be voluntary, but any travel expenses related to participation should be paid for by the government. This panel could also be used by the various agencies with responsibility for food safety -- HHS, USDA, and EPA -- to elicit consumer input.

The federal government should increase consumer participation in meetings by encouraging participation through conference calling. For example, FSIS held a National Advisory Committee for Meat and Poultry Inspection in which many members who couldn't travel to the meeting participated via conference call. Some observers also participated through conference call. This is a good way to include the many consumer constituents who would like to be involved in policy development, but cannot afford to travel, cannot travel due to a medical condition, cannot hire child care on the meeting date, or cannot take time off from work to participate.

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